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10/523,217	10/19/2005	Randolf Von Open	17601.38a.1	8379
57360	7590	66/01/2009	EXAMINER	
WORKMAN NYDEGGER			SONNETT, KATHLEEN C	
1000 EAGLE GATE TOWER,			ART UNIT	PAPER NUMBER
60 EAST SOUTH TEMPLE			3731	
SALT LAKE CITY, UT 84111				
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		06/01/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,217	<b>Applicant(s)</b> VON OEPEN ET AL.
	<b>Examiner</b> KATHLEEN SONNETT	<b>Art Unit</b> 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 March 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36 and 38-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 36 and 38-57 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-166/08)  
 Paper No(s)/Mail Date 3/20/2009
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 36, 38-40, 44, and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (Re 36,974) in view of Kim (US 5,810,884). Bonutti discloses an apparatus for facilitating sealing of a puncture formed in a proximal later surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first bore extending laterally therethrough and a filament having first and second free ends, the filament being slidably disposed through the first bore (see fig. 20), the bar being slideable relative to the filament. Bonutti discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end.

3. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Bonutti as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

4. Regarding claim 38, the device further comprises a push rod (82) disposed in the lumen proximal of the bar.

5. Regarding claim 39, the bar is cylindrical.

6. Regarding claim 40, the bar may be biodegradable (see col. 3, ll. 40-41).

7. Regarding claims 44 and 48, Bonutti discloses two bores (fig. 20). The bore (186) is being considered disposed in a central region of the bar.

8. **Claims 41-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Kim as applied to claim 36 above and further in view of Nash et al. (US 5,411,520).

Bonutti in view of Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned stated.

9. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered an equivalent alternative to an elastomeric material. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state with no filament therein, is thinner than the diameter of the filament in order to have a stronger grip on the

filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Bonutti to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

10. **Claims 45-47 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Kim as applied to claim 36 above and further in view of Rollero et al. (US 6,506,197). Bonutti in view of Kim discloses the invention substantially as stated above including the use of either a bore or an eyelet through which a filament is threaded since Kim teaches threading a filament (14) through an eyelet (104). Kim further teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both for additional control over the bar. Bonutti in view of Kim fails to disclose the filament slidably disposed through the first bore, then the eyelet, then back through the first bore.

11. Rollero et al. discloses that it is old and well known in the art to include a plurality of attachment points, such as holes, in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Bonutti. The filament is disposed through a central bore, then a bore in a distal region of the bar, then back to the central bore in order to provide a more secure attachment of the bar to the filament (see figs. 6a-6c). It would have been obvious to one of ordinary skill in the art to employ a plurality of attachment points through which the filament is slidably disposed as made obvious by Rollero et al. in the device of Bonutti so that suture can be attached to the bar more securely if desired.

12. Regarding claim 49, Rollero et al. makes obvious a plurality of bores wherein one of the bores is in a central region and one bore is disposed in a distal region of the bar.

13. **Claims 50, 51, 54-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchand (US 6,228,096) in view of Kim. Marchand discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first eyelet coupled to the bar (100; fig. 4b), a filament ("S") having a first and second free end (fig. 7), the filament being slidably disposed through the first eyelet, the bar being slidable relative to the filament. Marchand also discloses a delivery sheath in which the filament and bar are disposed as well as a push rod (40; fig. 8) disposed proximal of the bar but fails to disclose a first bore through which the filament is also removably disposed or a sharpened tip at the distal end.

14. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. Kim also teaches that it is well known to include a bore (103) on a bar which also includes an eyelet (fig. 9a). The bore allows for better steering of the bar as it is threaded along a filament. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Marchand as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. It would have also been obvious to include a bore on the bar as taught by Kim in order to better control steering of the bar during implantation.

15. Regarding claim 56, Marchand does not expressly disclose that the bar is made of a biodegradable material. However, biodegradable fixation members are very well known in the art and such a modification would have been obvious to one skilled in the art in order to increase biocompatibility of the device.

16. Regarding claim 57, Marchand discloses a tensioning device configured to hold the filament in a tensioned state (col. 3 ll. 65-col. 4 ll.10).

17. **Claims 52 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchand in view of Kim as applied to claim 50 above and further in view of Rollero (US 6,506,197). Marchand in view of Kim discloses the invention substantially as stated above including an eyelet and a bore as the suture attachment point on a bar but fails to disclose more than one eyelet.

18. Rollero et al. discloses that it is old and well known in the art to include a plurality of attachment points in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the proximal and distal regions when the bar is inserted using the delivery sheath of Marchand. It appears that the use of an eyelet versus a bore is merely a design consideration as they both serve the same function of providing an attachment point to the bar through which the flexible member may be threaded. Since Marchand uses an eyelet, it would have been obvious to one skilled in the art to employ a plurality of eyelets in the device of Marchand along with the bore taught by Kim to provide the plurality of attachment points taught by Rollero et al. so that suture can be securely attached to the bar if desired.

19. Regarding 52, Rollero et al. teaches threading the filament through the first attachment point, then through the second attachment point, and then back through the first attachment point (fig. 6c for example).

***Response to Arguments***

20. Applicant's arguments filed 3/12/2009 have been fully considered but they are not persuasive. Regarding the combination of Bonutti in view of Kim, Applicant argues that it would not have been obvious to one skilled in the art to add the sharpened tip taught by Kim to the delivery device of Bonutti because Bonutti discloses that it is preferable to insert the anchor directly through the soft tissue, not into an opening formed in the tissue. However, this is not found persuasive. Bonutti discloses that the anchor may have a slightly sharpened tip to push through tissue layers. Adding a sharpened tip to the delivery device will work in a similar manner to a sharpened anchor and is advantageous because the sharpened surface is removed so as not to aggravate surrounding tissue. Bonutti discloses forming a hole in bone using a drill and then using a separate delivery device to deliver the anchor and it appears to the examiner that Bonutti is merely pointing out that a preformed hole is not needed in the case of soft tissue since the sharpened anchor, or similarly a sharpened delivery device, can be used to separate the tissue enough to insert the anchor without pre-forming a hole.

21. Regarding the prior art of Marchand, Rollero and Kim, Applicant argues that the filament remains attached to the bar following deployment and therefore does not meet the claimed limitation of the bar being removable from and slid able relative to the filament. In order to meet the claimed limitation, the bar must only be capable of being removed from and slid able relative to the filament. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. For example, before the bar and filament are implanted into tissue, they are slid able relative to one another. Furthermore, after implantation, the bar can then be removed from tissue and slid relative to the filament.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/27/2009

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
5/29/09